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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,848	12/04/2001	Markus Haller	P-8572.00	7830
27581	7590	06/09/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/004,848	HALLER, MARKUS	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 30-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 46-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/27/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 3/24/05 is acknowledged.

Claims 30-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/24/05.

Specification

The disclosure is objected to because of the following informalities: it is assumed applicant is invoking 112 6th paragraph interpretation regarding the means plus function limitations in claims 46-49. The specification does not clearly set forth the structures that make up each of the means clauses. It is requested that applicant clearly indicate which structures constitute which means.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 and 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boydman (USPN 5,069,668) in view of Fischell (USPN 4,731,051).

It is noted that the means plus function recitations in claims 46-49 are being interpreted as such. It is assumed that applicant has invoked 112 6th paragraph. Additionally, it is asked above that applicant clearly identify which structures correspond to each means limitations since the instant specification does not clearly identify each means.

Regarding claims 1-4, 14-16, Boydman discloses a method and device for activating a drug delivery system that includes initiating a timer to time a lock out interval upon issuing a first dosage, receiving an input signal indicating a user request for a second dosage, rejecting the user request for the second dosage/flow rate change when received prior to expiration of the lock out interval and initiating the user request for the second dosage/flow rate change when received after expiration of the lock out interval. See figure 2 and 5:18-22. The timer is restarted when a bolus is given. See figure 2.

Regarding claims 22-26, it is considered inherent that the device includes a computer readable medium with instructions for carrying out the above. The medium is required and cannot be omitted for proper functioning of the device as disclosed.

Regarding claims 5-13, 17-21, 27-29, 46-53 Boydman fails to teach an external activation device in conjunction with an implantable drug delivery system

However, Fischell discloses an external activation device and implantable pump. See figure and 3:15+. The activation device limits the amount of drug the patient can administer.

At the time of the invention, it would have been obvious to incorporate the external activation device of Fischell into the system and method of Boydman. Both devices are

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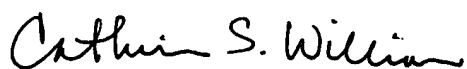
analogous in the art of subcutaneous drug delivery. Additionally, the motivation for the combination would have been in order to enable the system and method of Boydman to be used with an ambulatory patient or one that desires free range of movement such as an active adult or child thereby enhancing the patient's quality of life. Enhancing patient quality of life is a well known advantage in the art and well known by one skilled in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
June 7, 2005